



Appl. No. 09/938,667
Atty. Dkt. No. 092486-0102

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Jens PETERSEN

Title: POLYACRYLAMIDE HYDROGEL FOR THE
TREATMENT OF INCONTINENCE AND
VESICOURETAL REFLUX

Appl. No.: 09/938,667

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Examiner: Blessing M. FUBARA

Art Unit: 1618

Confirmation Number: 2505

PRE-APPEAL BRIEF REQUEST FOR REVIEW

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Commissioner for Patents
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Sir:

This Pre-Appeal Brief Conference Request is being filed together with a Notice of Appeal under the Pre-Appeal Brief Conference Pilot Program announced in the Official Gazette dated 12 July 2005. No Appeal Brief has been filed, and the total length of this Request is less than five pages.

REMARKS

The rejections of claims 129-147 over U.S. Patent No. 5,798,096 to Pavlyk in view of RU 2,148,957 to Sknar or U.S. Patent No. 6,335,028 to Vogel *et al.* are untenable because the conclusion of obviousness finds no record support. There is little disagreement as to the disclosure of Pavlyk, Sknar, and Vogel. The conflict lies in the conclusions to draw from these references, especially in view of the expert declaration evidence.

The claims are directed to a “method of treating urinary incontinence, comprising injecting into a urethra a hydrogel” with specifically defined rheological properties. Pavlyk discloses a penile implant material and contains no mention of urinary incontinence. Sknar discloses injection of polyacrylamide hydrogels into the *ureter*, not the urethra, to treat vesicoureteral reflux (“VUR”), and Vogel discloses use of microparticles for treating incontinence. These facts are not contested. Yet this disclosure does not suggest the treatment of “urinary incontinence, comprising injection into a *urethra*” the specifically recited hydrogel. The evidence of record, including declarations from experts in the field, establishes that the claimed invention contravenes conventional wisdom and is, therefore, non-obvious.

A. Pavlyk in view of Sknar

Pavlyk in view of Sknar does not render obvious the claimed invention for two reasons. First, Pavlyk and Sknar do not teach or suggest the recited hydrogel. Second, Sknar’s injection of polyacrylamide hydrogels into the *ureter* to treat vesicoureteral reflux (“VUR”) does not teach or suggest the treatment of urinary incontinence by “injecting into a *urethra* a hydrogel,” as explained by experts in the field.

1. Pavlyk and Sknar Do Not Teach Or Suggest The Recited Hydrogel

Neither Pavlyk nor Sknar suggests the recited hydrogel. Pavlyk’s polymer contains far more monomer than permitted by the claims. *See* Response filed 30 June 2009 at p. 15; Declaration Under 37 C.F.R. § 1.132 by Robert Lessél filed 11 June 2008 at ¶¶ 7, 8, 10, 11 (Lessél Decl.); Declaration of Dr. Ieva Ankorina-Stark Under 37 C.F.R. § 1.132 (Ankorina-Stark Decl.) filed 11 June 2008 at ¶¶ 13, 14. Pavlyk failed to recognize the presence of residual monomer or its significance. Lessél Decl. at ¶ 11. Accordingly, Pavlyk fails to teach or suggest the recited

hydrogel. Sknar fails to provide any details of its polymer, so it is mere speculation that it could somehow meet the requirements of the recited hydrogel.

2. One Of Skill In The Art Would Not Generalize From Use Of Bulking Agents For VUR To Use Of Bulking Agent For Urinary Incontinence

Neither Pavlyk nor Sknar suggests treating urinary incontinence by “injecting into a *urethra* a hydrogel,” as claimed. Sknar discloses injection of polyacrylamide hydrogels into the ureter to treat vesicoureteral reflux (“VUR”), and Pavlyk concerns itself with a penile implant material rather than treatment of any type of urinary incontinence (UI). Nonetheless, the Examiner contends that one of ordinary skill in the art would have generalized a method of treating one condition, VUR, to another, urinary incontinence, on the basis that both involve impeding the flow of urine.

This conclusion contradicts expert opinion. Specifically, Drs. Diamond and Dmochowski submitted declarations explaining that the person of ordinary skill in the art would not have generalized from the usage of a bulking agent to treat VUR to usage of the agent to treat urinary incontinence. *See* Declaration of David A. Diamond Under 37 C.F.R. § 1.132 (“Diamond Decl.”) filed 11 June 2008 and Declaration of Roger R. Dmochowski Under 37 C.F.R. § 1.132 (“Dmochowski Decl.”) filed 11 June 2008. Specifically, Dr. Diamond explains that VUR and total urinary incontinence have “very different pathology[ies],” and due to these different pathologies, one of skill in the art “would not have presumed or reasonably expected that a given demonstration of using a bulking agent to correct VUR [...] would be predictive of success in treating pediatric urinary incontinence with that bulking agent.” Diamond Decl. at ¶¶ 7-8. Dr. Dmochowski corroborates this opinion by explaining the anatomical differences underpinning the differences between VUR and urinary incontinence.

The Examiner discounts the Diamond Declaration stating that the declaration “centers on pediatric incontinence while the claims are not directed to treating pediatric incontinence,” but also admits that Dr. Diamond’s opinions “may” apply to adult incontinence. Final Office Action at pg. 11. This argument both misapprehends the Diamond Declaration and fails to give it the proper weight. Dr. Diamond addresses pediatric urinary incontinence simply because Sknar, a reference addressed by Dr. Diamond, is directed to treatment of VUR in children. Dr. Diamond’s opinions, however, also apply to urinary incontinence in adults, as explained in the Dmochowski Declaration. Moreover, the Examiner has provided no explanation as to how adult urinary incontinence differs

from pediatric urinary incontinence such as to undermine Dr. Diamond's opinions and, in fact, admits without explanation that the opinions "may" extend to adult incontinence.

With respect to the Dmochowski Declaration, the Examiner contends that, "because injecting hydrogel into the ostium impedes flow of urine, it is reasonable to expect that injecting hydrogel into the urethra would also impede flow of urine and this treat urinary incontinence." Final Office Action at pg. 11-12. This statement supplants expert opinion rather than explains how the expert opinion is flawed or inapplicable. Dr. Dmochowski opines that the person of ordinary skill in the art "would not have generalized from (i) documents usage of a bulking agent for treating VUR to (ii) a suggestion of using such a bulking agent to treat UI." Dmochowski Decl. at ¶ 13. The fact that Sknar reference may impede urine does nothing to undermine the conclusion that one of skill in the art simply "would not have generalized from [...] usage of a bulking agent for treating VUR to [...] using such a bulking agent to treat UI." Again, the Examiner does not explain why the opinions of Dr. Dmochowski are incorrect, but rather improperly seeks to undermine those opinions by simply stating an opposite conclusion.

B. Pavlyk in view of Vogel

The rejection based on Pavlyk in view of Vogel is flawed for two reasons. First, Vogel is directed to very different polymers than the hydrogel recited by the claims, and there is no reason for one of ordinary skill in the art to use Pavlyk's polymer based on Vogel. Second, neither Pavlyk nor Vogel suggests the recited hydrogel, which has specific rheological properties.

1. Vogel Does Not Suggest The Use Of Pavlyk's Polymer

The Examiner cited Vogel as treating urinary incontinence, because Pavlyk, as acknowledged by the Examiner, does not disclose the treatment of urinary incontinence. Final Office Action at pg. 5. Thus, Vogel is required for suggesting a treatment of urinary incontinence.

Yet one of ordinary skill in the art would find no hint in Vogel that Pavlyk's polymer could be used to treat UI. Indeed, Vogel's polymer microparticles are far different from the hydrogel recited by the claims, as explained in detail on pages 12-14 of the Response filed 30 June 2009. In sum, Pavlyk's polymer differs from Vogel's microparticles in every relevant way – types of material (hydrogel v. microparticles), content of polymer, chemical composition, molar ratio, presence of

residual monomer, complex viscosity, and elasticity modulus. One of ordinary skill in the art would, therefore, have no reason to substitute Pavlyk's polymer for Vogel's microparticles and would certainly not have any expectation of success in doing so.

2. Pavlyk and Vogel Do Not Teach Or Suggest The Recited Hydrogel

Vogel does not teach or suggest the recited hydrogel, as explained in detail in the Response filed 30 June 2009 at pages 6-7. Pavlyk also does not teach or suggest the recited polymer because it contains far too much monomer, as discussed above and in the Response filed 30 June 2009 at page 15. Thus, even if combined, Vogel and Pavlyk would still not teach or suggest the claimed invention.

The Examiner persists in stating that Pavlyk's polymer "meet[s] the limitations of the acrylamide hydrogels." Final Office Action at pg. 4. But this conclusion is incorrect and plainly rebutted by the Lessél and Ankorina-Stark Declarations, as discussed above. The Examiner has not satisfactorily "explain[ed] why this evidence is insufficient," as required. MPEP § 716.01(B); *In Re Sullivan*, 498 F.3d 1345, 1349 (Fed. Cir. 2007) ("[t]he claimed composition cannot be held to have been obvious if competent evidence rebuts the *prima facie* case of obviousness"). Accordingly, there is insufficient basis to disregard the reasoned opinions and facts established by the declarations.

CONCLUSION

The remaining rejections are untenable and should be withdrawn and a Notice of Allowance issued without further delay.

Respectfully submitted,

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